



Animal Care

www.aphis.usda.gov/animal_welfare

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Factsheet

USDA United States Department of Agriculture

Animal and Plant Health Inspection Service
APHIS 41-05-011

Federal Oversight of Animal Use in Research Facilities

The three agencies involved with overseeing the welfare of animals used in research are the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) and two U.S. Department of Health and Human Services agencies: the National Institutes of Health (NIH) and the Food and Drug Administration (FDA). While each agency has distinct authorities and areas of responsibility, they also collaborate to make sure laboratory animals receive the level of care required under Federal regulations. All three agencies also require research facilities to have an Institutional Animal Care and Use Committee (IACUC). This oversight body is empowered to conduct facility inspections, investigate complaints of inhumane animal care, and approve or suspend animal research activity.

■ APHIS

APHIS enforces the Animal Welfare Act (AWA), which was passed by Congress in 1966. The AWA is the foundation of humane animal care in research facilities. This law requires all facilities that use certain warmblooded animals (except rats, mice, and birds) in research to provide veterinary care, an appropriate diet, potable water, clean and structurally sound housing, protection from weather and temperature extremes, and safe handling during transportation. All non-Federal facilities must register with APHIS and are subject to unannounced inspections by APHIS Animal Care (AC) personnel. AC inspectors observe and assess animal health and thoroughly review all AWA-required records and documentation. Every research facility must be inspected at least once annually, but more inspections may be required. Serious or repeated instances of noncompliance may result in an enforcement action. In addition to regulatory responsibilities, AC offers and supports many training and educational programs on humane animal care.

■ NIH

NIH is the largest source of funding for medical research in the world, and is made up of 27 Institutes and Centers, each with a specific research agenda, often focused on particular diseases or body systems. Before NIH and other Public Health Service (PHS) agencies award a grant or contract that involves the use of animals, the recipient institution and all performance sites using animals must have an Animal Welfare Assurance approved by NIH's Office of Laboratory Animal Welfare (OLAW). Animals used in funded activities must receive humane care in accordance with the PHS Policy on Humane Care and Use of Laboratory Animals. Under the regulatory authority of the Health Research Extension Act, OLAW monitors funded institutions by evaluating self-reported noncompliance, annual reports, and potentially by conducting site visits. If noncompliance is identified, OLAW gives the institution a reasonable opportunity to take corrective action. If no action is taken, OLAW may restrict or withdraw the institution's Assurance agreement which precludes the receipt of PHS funds for the conduct of animal activities. OLAW also supports educational programs and investigates allegations concerning research animal welfare to ensure the humane care and use of animals in PHS-supported research, testing, and training.

■ FDA

The FDA is responsible for ensuring good laboratory practice in FDA-regulated product development. When animal testing is done to support applications for such products, manufacturers and sponsors must follow FDA's regulation, Good Laboratory Practice (GLP) for Nonclinical Laboratory Studies. Under authority of the Federal Food, Drugs, and Cosmetics Act, FDA's Office of Regulatory Affairs conducts unannounced inspections of research facilities every 2 or 3 years depending on the number of GLP studies being performed. Findings of noncompliance with GLP standards may result in rejection of data and the denial of a product for market. There are five animal research facilities in FDA; all are accredited by the Association for the Assessment and Accreditation of Laboratory Animal Care International, all are OLAW assured, and those that conduct research with regulated species are registered with USDA. FDA investigators who use animals in research and testing are required to receive training on humane animal care and use.

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■ Working Together

APHIS, NIH, and FDA have a longstanding Memorandum of Understanding (MOU) setting forth a framework for reciprocal cooperation. This agreement is intended to maintain and enhance agency effectiveness while avoiding duplication of efforts to achieve required standards for the care and use of laboratory animals. The MOU also details an agreement to exchange information resulting from investigations, inspections, or site visits as well as information about actions taken in response to these findings. This enables the agencies to coordinate evaluations and reduce regulatory burden and redundancy. Matters of serious animal welfare concern are shared among the agencies. Some incidents or noncompliances are not mutually reported because the agencies operate under differing regulatory authorities and mechanisms of oversight. In addition, routine information from inspections, investigations, and record reviews is not generally shared.

■ More Information

For more specific information about the AWA and its regulations and standards, visit APHIS' Animal Care Web site at www.aphis.usda.gov/animal_welfare. To learn more about NIH, FDA, and their respective regulations, visit www.nih.gov and www.fda.gov.

To view the MOU between these agencies, please go to <http://grants.nih.gov/grants/olaw/references/finalmou.htm>.

